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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0722]

Fresenius Kabi USA, LLC, et.al.; Withdrawal of Approval of Six Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of six abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065111	Kanamycin Sulfate Injection, Equivalent to (EQ) 500 milligrams (mg) base/2	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047

Application No.	Drug	Applicant
	milliliters (mL) and EQ 1 gram (g) base/3 mL	
ANDA 079107	Levetiracetam Solution, 100 mg/mL	Tolmar, Inc., 701 Centre Ave., Fort Collins, CO 80526
ANDA 201832	Nimodipine Capsules, 30 mg	Sofgen Pharmaceuticals, LCC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180
ANDA 202418	Lamivudine and Zidovudine Tablets, 150 mg; 300 mg	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 202743	Azelastine Hydrochloride (HCl), Metered Spray, 0.2055 mg/spray	Padagis US LLC., U.S. Agent for Padagis Israel Pharmaceuticals Ltd. (formerly known as Perrigo Israel Pharmaceuticals Ltd.), 3940 Quebec Avenue North, Minneapolis, MN 55427
ANDA 203937	Fludeoxyglucose F18 Injection, 4-500 millicurie (mCi)/mL	Hot Shots NM, LLC, DBA Midwest Positron Technology, LC, 2017 E. Kimberly Rd., Suite C, Davenport IA 52807

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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